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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,713	06/13/2000	MARION J. G. BUSSEMAKERS	1619.0020001	6311

7590 06/25/2004
Stern, Kessler, Goldstein & Fox P.L.L.C.
1100 New York Avenue, N.W. Suite 600
Washington, DC 20005

EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/402,713

Applicant(s)

BUSSEMAKERS, MARION J. G.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4-14 and 24-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4-14 and 24-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/2/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Notice to comply</u> . |

DETAILED ACTION

The amendment filed on 4/2/2004 is acknowledged.

Claims 2, 4, 6-8, and 29-35 are amended, and claims 39-45 are new. Claims 2, 4-14 and 24-45 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of rejection.

Specification

The objection of disclosure is due to the informalities in the drawing description and also due to the restriction site for restriction endonuclease at page 7 is withdrawn in view of the amendment.

However, the specification remains objected because the DNA sequence at Fig. 4 does not have a sequence identifier. The notice to comply that was attached in the last Office action is attached again.

Information Disclosure Statement

The information disclosure statement filed 4-2-2004 has been considered, and a copy of the 1449 is attached with this Office action.

Claim Rejections - 35 USC § 112

The rejection of claims 2, 4-14, 24-38 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of the amendment.

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Claims 2, and 11-26 remain rejected, and new claims 39-45 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is made because the base claims 2 (e), and 39 (e) are drawn to a genus of various hybridizing nucleic molecules. This rejection will be withdrawn if the claims are drawn to primer or probe capable of detecting the nucleic acid molecules i.e. the Markush member (a)-(e) in the base claims and the dependent claims inside prostate cancer tissue. See the metes and bounds rejection below.

Applicant argues that encoding prostate cancer antigen (PCA3) is deleted from the claims, therefore the rejection is moot. However, the previous Office action stated at page 6 that the claims lack written description due to the genus of hybridizing nucleic acid molecules without adequate written description. The specification does not describe what kind of activity is associated with the genus of nucleic acid molecules being claimed.

The applicable standard for the written description requirement can be found: MPEP 2163; *University of California v. Eli Lilly*, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; *Enzo Biochem Inc. v. Gen-Prove Inc.*, 63 USPQ2d 1609; and *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the respective base claims is hybridization conditions. It is noted that the genus (e) also hybridizes to one or more nucleotides over-expressed in prostate cancer tissues compared to the recited control. However, this does not appear to be the function of the hybridizing molecules because what will hybridize to the nucleic acid of (a)-(d) depends on its structure, not function of the nucleic acid molecules.

Claims 2, and 11-14 remain rejected, and new claims 39-45 are newly under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

This rejection is made because the base claims 2 (e), and 39 (e) are drawn to a genus of various hybridizing nucleic molecules. If the claims are drawn to primer or probe, this rejection will be withdrawn. See the metes and bounds rejection below.

Applicant argues that encoding prostate cancer antigen (PCA3) is deleted from the claims, therefore the rejection is moot. However, the previous Office action stated at page 6 that the claims lack written description due to the genus of hybridizing nucleic acid molecules without adequate written description. The specification does not describe what kind of activity is associated with the genus of nucleic acid molecules being claimed.

The specification fails to teach how to make the various nucleic acids, since the specification does not teach what activity to look for. Hybridization is not an activity of nucleic acid molecules, but it is another way of saying the structure of a nucleic acid molecule is similar because the structure determines what would be hybridizes to a given nucleic acid molecules.

The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 2, 4-14 and 24-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is made because the new limitation of base claims "An isolated nucleic acid molecule which functions as a probe or primer for the selective detection of prostate cancer tissue **comprising** a polynucleotide sequences selected from the group consisting of" with the Markush member listed in the base claims and dependent claims. It appears that some of the Markush members for example SEQ ID NO: 1, 2, 4, and 6 are not primers or probe but either a full-length cDNA encoding a human protein or a cDNA

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corresponding to a non-coding mRNA, which is different from primer or probe. Further the transitional phrase “**comprising**” after “cancer tissue” makes confusing the scope of the claimed invention confusing. It is not clear whether a primer or probe capable of detecting the Markush member (a)-(e) in a prostate cancer tissue is claimed or an isolated nucleic acid comprising the nucleic acid of (a)-(e) is being claimed. If primer or probe is claimed, then nucleic acid contained in plasmid deposited in a depository could not be in prostate cancer tissue. Further, the new claims 39 is drawn to a sequence longer than the specific sizes in claims 44, and 45. The dependent claims should have all the limitation of the base claim. Therefore, property boundary of claims 39-45 are not reasonably set, therefore indefinite.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will


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the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina C Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


LARRY R. HELMS, PH.D.
PRIMARY EXAMINER

MISOOK YU, Ph.D.
Examiner
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